IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094**
	:	**24-md-3094**
THIS DOCUMENT RELATES TO:	:	
ALL ACTIONS/ALL CASES	:	

DEFENDANT NOVO NORDISK'S OPPOSITION
TO PLAINTIFFS' MOTION TO SUPPLEMENT THE RECORD
AS TO CROSS-CUTTING ISSUE NO. 1

This Court should deny Plaintiffs' untimely and meritless Motion to Supplement the Record for the reasons set forth in the Opposition filed by Eli Lilly and for the foregoing additional reasons.

At the outset, Plaintiffs' Motion ignores the carefully delineated process this Court established to decide Issue 1, focused on determining the reliability of Plaintiffs' proposed methods for diagnosis of gastroparesis. This Court decided that inquiry was a question for the experts, not one that depended on company records. As a result, after extensive briefing, argument, and consideration, this Court denied discovery into company evidence irrelevant to Issue 1. *See* CMO 18, ECF No. 235, ¶¶ 6, 14 (granting Defendants' request for early motion practice as to Issue 1 related to *expert* discovery and delaying regulatory and company discovery until Issue 2); Defs.' Letter Brief, ECF No. 174 at 4 ("Finally, the gastroparesis diagnosis question is unique in that it can be addressed without fact discovery."). Plaintiffs' ill-founded attempt to retread this Court's orders by seeking to "reopen" the record at this late time should be rejected out of hand.

Not only does the document have no connection to the reliability of Plaintiffs' experts' methodology to diagnose gastroparesis, but as Lilly points out in its filing, the substance of the document does not support Plaintiffs' position. A full reading of that document reaffirms that neither symptoms alone, nor retained gastric food, are reliable methods to diagnose gastroparesis. Plaintiffs' proposed supplemental document is therefore neither relevant nor helpful to their position.

Furthermore, the primary methodology put forward in Plaintiffs' experts' reports is predicated on their belief that it is possible to diagnose gastroparesis based on symptoms alone (without the need for any testing). *See* Raines Rpt., ECF No. 360-6 at 14; Siegel Rpt., ECF No.

360-17 at 25. As demonstrated at the May 14, 2025 Rule 702 hearing, that symptom-based methodology was never put through testing (Hr'g Part 1, ECF No. 419 at 227:21-229:15; Hr'g Part 2, ECF No. 413 at 54:5-55:2), was not peer reviewed (ECF No. 419 at 223:2-224:17; ECF No. 413 at 51:23-52:1), has been rejected by the consensus statements and authoritative clinical guidelines (ECF No. 419 at 199:24-200:12; ECF No. 413 at 104:21-105:12), and is shown by the available evidence to be wrong nearly two-thirds of the time (ECF No. 413 at 94:24-95:5; *see also* Novo Nordisk's Mot. to Exclude Drs. Raines and Siegel, ECF No. 360-1 at 15, 21; Defs.' Joint Reply to Exclude Drs. Raines and Siegel, ECF No. 385 at 8). Indeed, all consensus statements on the diagnosis of gastroparesis state that such diagnosis requires objective evidence of delayed gastric emptying, as demonstrated by appropriately performed scintigraphy, breath test, or capsule motility study. ECF No. 360-1 at 5-8; Camilleri (2022), ECF No. 360-4. Nothing in the Lilly document contradicts these facts; on the contrary, the document plainly states that "nausea and vomiting are non-specific with a wide variety of differential diagnoses." ECF No. 447-2 at 16.

Plaintiffs' experts' methodology also is predicated on an unfounded assumption that a patients' gastrointestinal symptoms must be caused by a medication's effect on gastric emptying, as opposed to a medication effect within the brain / central nervous system (for example, the nausea centers in the brain). As discussed in Defendants' briefing, Plaintiffs' experts failed to consider this issue and even failed to review the literature discussing the mechanisms by which GLP-1RA medicines may induce gastrointestinal symptoms, including effects at the level of the central nervous system that are entirely independent from gastric emptying. ECF No. 360-1 at 21; ECF No. 385 at 8-9; ECF No. 419 at 208:4-217:18. Again, nothing in the Lilly document bridges this analytical gap in Plaintiffs' experts' methodology.

Finally, as discussed in Defendants' briefing, Plaintiffs' experts conceded that diagnosis of *chronic* gastroparesis requires a gastric emptying study, consistent with consensus guidelines. That concession covers the vast majority of Plaintiffs in this litigation, who assert symptoms persisting even after GLP 1-RA treatment cessation, and is not altered or affected by the substance of the Lilly document. ECF No. 360-1 at 12-13; Eli Lilly's Mot. to Exclude Gastroparesis Opinions, ECF No. 361-1 at 14.

Accordingly, Plaintiffs Motion to Supplement should be denied.

Dated: July 28, 2025

Respectfully Submitted,

/s/ Loren H. Brown

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CERTIFICATE OF SERVICE

I hereby certify that, on July 28, 2025, a true and correct copy of the foregoing Defendant Novo Nordisk's Opposition to Plaintiffs' Motion to Supplement the Record as to Cross-Cutting Issue No. 1 was electronically filed using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Loren H. Brown
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